



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Carl J. WHEELER

Appl. No.: 10/748,853

Filed: December 30, 2003

For: **Complex Cationic Lipids Having  
Quaternary Nitrogens Therein**

Art Unit: *To Be Assigned*

Examiner: *To Be Assigned*

Atty. Docket: 1530.0260002

**Information Disclosure Statement under 37 C.F.R. § 1.97(b)**

Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97, and 1.98. Copies of documents AA1-AK1 and AA2 are not provided in accordance with the U.S. Patent and Trademark Office pre-OG notice of July 11, 2003, which states "the Office hereby waives the requirement under 37 CFR 1.98 (a)(2)(i) for submitting a copy of each cited U.S. patent and each U.S. patent application publication for all U.S. national patent applications filed after June 30, 2003." Copies of documents AL1-AP1 and AL2-AN2 were cited by or submitted to the Office in an Information Disclosure Statement that complies with 37 C.F.R. § 1.98(a)-(c) in Application No. 09/092,486, filed June 5, 1998, now U.S. Patent No. 6,670,332 B1, which is relied upon for an earlier filing date under 35 U.S.C. § 120. Thus, copies of these documents are not attached. 37 C.F.R. § 1.98(d). Copies of documents AR1-AT1, AR2-AT2, and AR3-AS3 are provided.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicant has listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicant reserves the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

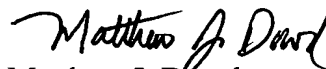
This Information Disclosure Statement is being filed within three months of the date of filing. No statement or fee is required.

It is respectfully requested that the Examiner initial and return a copy of the enclosed PTO 1449, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

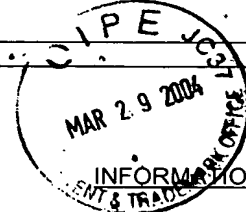


Matthew J. Dowd  
Agent for Applicant  
Registration No. 47,534

Date: March 29, 2004

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 <p>FORM PTO-1449</p> <p><b>INFORMATION DISCLOSURE STATEMENT</b></p>				ATTY. DOCKET NO. 1530.0260002		APPLICATION NO. 10/748,853	
				FIRST NAMED INVENTOR Wheeler, C.J.			
				FILING DATE December 30, 2003		ART UNIT To Be Assigned	
<b>U.S. PATENT DOCUMENTS</b>							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA1	2,368,208	01/30/1945	Epstein			12/16/1940
	AB1	3,265,719	08/09/1966	Cowen <i>et al.</i>			12/28/1959
	AC1	4,864,060	09/05/1989	Karalis <i>et al.</i>			08/31/1987
	AD1	5,049,386	09/17/1991	Eppstein <i>et al.</i>			05/15/1990
	AE1	5,068,431	11/26/1991	Karalis <i>et al.</i>			05/15/1989
	AF1	5,144,060	09/01/1992	Morita <i>et al.</i>			08/15/1990
	AG1	5,264,618	11/23/1993	Felgner <i>et al.</i>			04/16/1991
	AH1	5,279,833	01/18/1994	Rose			04/04/1990
	AI1	5,334,761	08/02/1994	Gebeyehu <i>et al.</i>			08/28/1992
	AJ1	5,869,715	02/09/1999	Nantz <i>et al.</i>			09/27/1995
	AK1	6,075,012	06/13/2000	Gebeyehu <i>et al.</i>			02/11/1994
<b>FOREIGN PATENT DOCUMENTS</b>							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL1	WO 91/17424	11/14/1991	WIPO			Yes No
	AM1	JP 03-258900	11/19/1991	Japan			X Yes No
	AN1	WO 94/05624	03/17/1994	WIPO			Yes No
	AO1	WO 95/14381	06/01/1995	WIPO			Yes No
	AP1	WO 95/14651	06/01/1995	WIPO			Yes No
<b>OTHER (Including Author, Title, Date, Pertinent Pages, etc.)</b>							
	AR	1	Felgner, P., <i>et al.</i> , "Lipofection: A highly efficient, lipid-mediated NDA-transfection procedure," <i>Biochem.</i> 84:7413-7417, American Chemical Society (1987)				
	AS	1	Felgner, J., <i>et al.</i> , "Enhanced Gene Delivery and Mechanism Studies with a Novel Series of Cationic Lipid Formulations," <i>J. Biol. Chem.</i> 269:2550-2561, American Society for Biochemistry and Molecular Biology (January 1994)				
	AT	1	Nabel, G., <i>et al.</i> , "Immunotherapy of Malignancy by <i>In Vivo</i> Gene Transfer into Tumors," <i>Human Gene Ther.</i> 3:399-410, Mary Ann Liebert, Inc. (1992)				
EXAMINER					DATE CONSIDERED		
<b>EXAMINER:</b> Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.							

FORM PTO-1449

INFORMATION DISCLOSURE STATEMENTATTY. DOCKET NO.  
1530.0260002APPLICATION NO.  
10/748,853FIRST NAMED INVENTOR  
Wheeler, C.J.FILING DATE  
December 30, 2003ART UNIT  
To Be Assigned**U.S. PATENT DOCUMENTS**

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA2	6,670,332 B1	12/30/2003	Wheeler			06/05/1998
	AB						
	AC						
	AD						
	AE						
	AF						
	AG						
	AH						
	AI						
	AJ						
	AK						

**FOREIGN PATENT DOCUMENTS**

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL2	WO 96/22379	07/25/1996	WIPO			Yes No
	AM2	EP 0 747 351	12/11/1996	Europe			Yes No
	AN2	WO 96/40961	12/19/1996	WIPO			Yes No
	AO						Yes No
	AP						Yes No


**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

	AR	<u>2</u>	Rosenthal, A., <i>et al.</i> , "A Synthetic Inhibitor of Venom Lecithinase A," <i>J. Biol. Chem.</i> 235:2202-2206, American Society for Biochemistry and Molecular Biology (1960)
	AS	<u>2</u>	Solodin, I. and Heath, T.D., "Synthesis of Novel Cationic Lipids with a Guanidine Group. Cationic Lipids 3," <i>Synlett</i> 7:617-618, Georg Thieme Verlag (July 1996)
	AT	<u>2</u>	Solodin, I. and Heath, T.D., "Synthesis of Amphiphilic Piperidinium Derivatives. Cationic Lipids 4," <i>Synlett</i> 7:619, Georg Thieme Verlag (July 1996)

EXAMINER

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		Page 3 of 3	
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	AA						
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	AK						

FOREIGN PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
AR	<u>3</u>	Solodin, I. , <i>et al.</i> , "Synthesis of Amphiphilic Derivatives of N-Methyldiethanolamine. Cationic Lipids 5 <sup>1</sup> ," <i>Synlett</i> 7:620, Georg Thieme Verlag (July 1996)	
AS	<u>3</u>	Wheeler, C.J., <i>et al.</i> , "Converting an alcohol to an amine in a cationic lipid dramatically alters the co-lipid requirement, cellular transfection activity and the ultrastructure of DNA-cytofectin complexes," <i>Biochim. Biophys. Acta</i> 1280:1-11, Elsevier Science B.V. (April 1996)	
AT			

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